K011525

JUL 16 2001

510(k) Summary

1) Submitter's Name Address, contact

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Contact Person: Jack A. Maggiore, PhD
BIOSAFE Laboratories, Inc.
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Date Prepared: May 16, 2001

2) Device Name

Proprietary Name: SAFE AT HOME TSH
Thyroid Stimulating Hormone
Blood Collection and Transport System

Common Name: Capillary blood self-collection and transportation system for TSH

Classification Name: Thyroid Stimulating Hormone
(21 CFR 862. 1690)

3) Predicate Device

BIOSAFE Capillary Blood Transport System for Testing Thyroid Stimulating Hormone (TSH) (K003752).

4) Device Description

The device is a kit containing the materials necessary to self-collect a whole blood capillary sample into a blood transport device for storage and transport to a certified clinical laboratory for testing thyroid stimulating hormone (TSH). The kit is comprised of a blood transport device in a foil pouch, alcohol prep pad, disposable lancets, gauze pad, bandage strip, collection instructions, insulated shipping box, leakproof bag, return prepaid envelope, and a patient test authorization form.

5) Intended Use

The SAFE AT HOME TSH Thyroid Stimulating Hormone Blood Collection and Transport System is intended for prescription distribution, and is a home-use device for collection and transportation of capillary blood for *in vitro* diagnostic quantitative determination of TSH. The device will be used for measuring whole blood TSH levels in human adults. This device is not intended for the diagnosis of thyroid disease in neonates.

Continued on next page

510(k) Summary, *continued*

6) Comparison to predicate device	The *SAFE AT HOME TSH Thyroid Stimulating Hormone Blood Collection and Transport System* has technological characteristics and an intended use that are substantially equivalent to that of the predicate device, BIOSAFE Capillary Blood Transport System for Testing TSH. The SAFE AT HOME TSH System provides components that permit collection, storage, and transportation of a capillary whole blood sample to a certified clinical laboratory for TSH analysis. Both kits are intended for testing blood for the *in vitro* diagnostic laboratory determination of TSH. The laboratory analysis for the BIOSAFE System, uses Nichols Institute Diagnostics 3rd Generation TSH Chemiluminescence Immunoassay for the determination of TSH (K881443). Determination of professionally collected capillary whole blood TSH using the BIOSAFE System (BTS) was previously shown to provide substantially equivalent values to serum TSH values using the Nichols Institute Diagnostics 3rd Generation Chemiluminescence Immunoassay (K003752). Results of clinical trials have further shown that self-collected capillary samples into the BIOSAFE BTS by a lay user provides TSH results that are substantially equivalent to professionally collected capillary samples when analyzed for TSH using the Nichols Institute Diagnostics 3rd Generation Chemiluminescence Immunoassay.
7) Performance Studies	Determination of self-collected capillary whole blood TSH using the BIOSAFE *Blood Collection and Transport System* (BTS) is substantially equivalent to professionally collected capillary whole blood using the BTS and analyzing the sample for TSH using the Nichols Institute Diagnostics 3rd Generation Chemiluminescence Immunoassay. Performance studies were conducted on self-collected blood samples from lay users (volunteer Study subjects) at four different geographical sites in three different time zones. A corresponding venous blood sample and a professionally-collected capillary sample were collected by the health care professional in order to compare whole blood sample results to those obtained from capillary blood samples collected on the BIOSAFE *Blood Collection and Transport System*. All samples collected were mailed directly back to BIOSAFE Laboratories for determination of TSH by Nichols Institute Diagnostics 3rd Generation Chemiluminescence Immunoassay.
8) Test Summary	Performance characteristics studied included precision and correlation. In addition, the BIOSAFE *Blood Collection and Transport System* for TSH determination was evaluated for reagent and sample stability when exposed to abusive conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 1 6 2001

Jack A. Maggiore, Ph.D.
Director, Clinical Trials
BIOSAFE Laboratories, Inc.
100 Field Drive, Suite 240
Lake Forest, Illinois 60045

Re: K011525
Trade Name: SAFE AT HOME TSH Thyroid Stimulating Hormone Blood Collection and Transport System
Regulation Number: 21 CFR § 862.1690 Regulatory Class: II Product Code: JLW
Regulation Number: 21 CFR § 862.1675 Regulatory Class: II Product Code: JKA
Dated: May 16, 2001
Received: May 17, 2001

Dear Dr. Maggiore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

C. Indications for Use Statement

The SAFE AT HOME TSH Thyroid Stimulating Hormone Blood Collection and Transport System is intended for prescription distribution, and is a home-use device for collection and transportation of capillary blood for *in vitro* diagnostic quantitative determination of TSH. The device will be used for measuring whole blood TSH levels in human adults. This device is not intended for the diagnosis of thyroid disease in neonates.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011525

[X] Prescription Use